UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Eli Lilly and Company, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

Federal Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction

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INTRODUCTION

Congress authorized the Food and Drug Administration (FDA) to determine whether a drug is "in shortage in the United States." FDA's determination of a drug shortage can trigger a variety of statutory mechanisms designed to alleviate the shortage and provide additional flexibilities to mitigate the disruption the shortage may cause. As relevant here, one such mechanism involves compounded drugs—medications that are not approved by FDA, which means the agency does not verify their safety, effectiveness, or quality before they are marketed. Ordinarily, the Federal Food, Drug, and Cosmetic Act (FDCA) restricts the compounding of drugs that are essentially copies of FDA-approved drugs. When FDA determines that there is a nationwide shortage of a particular drug, however, the FDCA temporarily allows certain compounding during the shortage. From 2022 until recently, FDA deemed tirzepatide injection products—approved drugs manufactured and marketed by Eli Lilly and Company (Lilly) under the names Mounjaro (for type 2 diabetes) and Zepbound (for obesity and sleep apnea)—to be in shortage. Thus, during the shortage, the FDCA's copies provisions did not restrict certain compounding of tirzepatide.

After considering evidence from multiple sources—including data provided by Lilly and information submitted by Plaintiffs and individual patients and pharmacies—FDA determined in December 2024 that the tirzepatide shortage was resolved. To avoid disrupting ongoing patient treatment and promote an orderly transition, FDA also announced that it would temporarily not take action against compounders for certain violations of the FDCA. Plaintiffs, a trade association that represents drug compounders and a pharmacy engaged in compounding, now challenge FDA's determination that the tirzepatide shortage has been resolved, arguing both that the shortage persists and that there were procedural defects in FDA's determination. Plaintiffs seek injunctive relief to stay FDA's determination and to prevent FDA from taking certain actions related to compounding tirzepatide products.

Plaintiffs have not made the extraordinary showing required to enjoin FDA's decision. First, Plaintiffs fail to establish a likelihood of success on their claim that FDA's shortage determination was arbitrary and capricious. FDA correctly evaluated Lilly's detailed information

about its supply and demand, which demonstrated Lilly is fulfilling all orders while maintaining a surplus of [redacted]. FDA also considered the available information from compounding pharmacies regarding the volume of compounding occurring and determined that Lilly's supply of [redacted] exceeded even a generous estimate. Plaintiffs' scattershot claims of FDA "misunderstanding" data all miss the mark, and FDA's determination that the tirzepatide shortage was resolved was more than reasonable.

Second, Plaintiffs fail to establish a likelihood of success on their claim that FDA was required to engage in notice-and-comment rulemaking to determine whether the tirzepatide shortage was resolved. FDA's decision was plainly an adjudication under the Administrative Procedure Act (APA). Far from establishing new law or policy that applies only prospectively (as a rule would), FDA resolved a discrete controversy by applying the statutory definition of "shortage" to a particular set of facts about the supply and demand of tirzepatide. Moreover, FDA has discretion to choose whether to proceed by rulemaking or adjudication, and the statutory authority at issue here and the facts of this case left FDA with only one viable option: adjudication. The statute requires the agency to keep the shortage list "up-to-date," prohibits the agency from publicly disclosing the vast majority of the information that it must consider in making its determinations, and authorizes FDA to keep confidential even the existence of its decision. In this case, those requirements were incompatible with notice-and-comment rulemaking. And even if notice-and-comment rulemaking were required, any error was harmless because Plaintiffs and the public had ample opportunity to submit information.

Finally, Plaintiffs' motion should be denied because the balance of equities and public interest weigh heavily against a preliminary injunction. The public has an interest in the greater safety protections that apply to FDA-approved drugs but not to compounded drugs. Further, an injunction would upset the balance Congress struck between incentivizing drug development by providing a market advantage to FDA-approved drugs and temporarily allowing certain compounding during a shortage.

For all of these reasons, Plaintiffs' motion for a preliminary injunction should be denied.

BACKGROUND

I. Statutory Background

A. FDA's regulation of drug manufacturing

The FDCA generally prohibits the introduction of a "new drug" into interstate commerce without FDA approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application (NDA). *Id.* § 355(b)(1). FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" (cGMP), which "assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Parts 210, 211. An NDA approval has significant effects on third parties: for example, for certain new drug approvals, the statute prohibits approvals of other manufacturers' applications for drugs using the same active moiety for five years (often referred to as "exclusivity" for the first drug approved). *See* 21 U.S.C. § 355(c)(3)(E)(ii).

Drug compounding is "a process by which a pharmacist or doctor combines, mixes or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Compounded drugs that meet certain conditions specified by the statute are not subject to the safety requirements that apply to FDA-approved drugs. Unlike FDA-approved drugs, compounded drugs do not, for example, "undergo[] FDA premarket review for safety, effectiveness, and quality." ECF No. 65-1 (Mem.) at 10. Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a ("503A" compounders) are not required to follow cGMP, among other things. Under 21 U.S.C. § 353b, on the other hand, outsourcing facilities ("503B" compounders) are subject to cGMP, registration, and product reporting requirements. Of particular importance here, the FDCA restricts both types of compounders from producing compounded drugs that are "essentially a

copy" of an FDA-approved drug. 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5). This statutory restriction "works to protect the new drug approval process and, by extension, provides a market advantage to FDA-approved drugs" over compounded drugs. *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 71 (D.D.C. 2019). But the restrictions that typically apply to compounding copies of an approved drug are temporarily lifted when the drug appears on the drug shortage list. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5).

B. Drug shortages

The FDCA defines a "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2). Congress requires FDA to "maintain an up-to-date list of drugs that are determined by [FDA] to be in shortage in the United States." 21 U.S.C. § 356e; *see* 21 C.F.R. § 314.81(b)(3)(iii)(*f*) (adopting the definition of "shortage" from 21 U.S.C. § 356c(h)(2)). Congress recognized that FDA must consider drug manufacturers' confidential commercial information and trade secrets to determine the status of a shortage. To that end, Congress provided that "[n]othing in this section alters or amends" 18 U.S.C. § 1905 or 5 U.S.C. § 552(b)(4), which protect such information from disclosure. 21 U.S.C. § 356e(c)(2). Congress also empowered FDA to "choose not to make information collected under this section publicly available" if doing so would "adversely affect the public health," such as where disclosing the information would "increas[e] the possibility of hoarding" the drug. *Id.* § 356e(c)(3).

When a drug appears on the drug shortage list, certain restrictions that typically apply to compounding copies of the approved drug are temporarily lifted. As is relevant here, the limitation on 503B pharmacies producing an "identical or nearly identical" product to an approved drug does not apply when a drug appears on the shortage list. *Id.* §§ 353b(a)(5), (d)(2)(A); *see also id.* § 353b(a)(2)(A)(ii) (exemption from limitation on compounding using bulk drug substances). The limitation on 503A pharmacies producing "drug products that are essentially copies" of approved drugs does not apply to drugs on the shortage list because FDA considers those drugs not "commercially available." *Id.* § 353a(b)(1)(D).

II. Factual and Procedural Background

In May 2022, FDA approved Lilly's NDA for Mounjaro. *See* ECF No. 32-1 (Decl. Order) at 4. Under 21 U.S.C. § 355(c)(3)(E)(ii), FDA generally may not approve an NDA for a drug product containing tirzepatide as its active moiety from any other manufacturer until 2027. Due to high demand for the drug that exceeded nationwide supply, FDA added Mounjaro to the drug shortage list in December 2022. Decl. Order 4. FDA approved Zepbound in November 2023 and for the same reason added it to the drug shortage list in April 2024. *Id.*[1]

FDA initially declared the shortage resolved on October 2, 2024. Shortly thereafter, Plaintiffs filed a complaint challenging that decision and, on October 8, 2024, moved to preliminarily enjoin it. ECF Nos. 1, 7. Three days later, Defendants moved to voluntarily remand this case to the agency for reevaluation. ECF No. 27. Defendants made clear that Plaintiffs could submit additional information regarding tirzepatide's availability for FDA's consideration. *Id.* at 4. The Court granted Defendants' motion and stayed proceedings. ECF No. 28.

On December 19, 2024, FDA issued a declaratory order finding that the shortage of tirzepatide was resolved. Based on its review of "detailed information and data regarding" Lilly's production and inventory of the drugs "at various points in time," FDA determined that Lilly was meeting or exceeding current demand for the products. Decl. Order 2. Moreover, FDA found that Lilly had "developed reserves" of "finished product" and "significant units of semi-finished product," and that Lilly had plans for "substantial additional production" in the near future. *Id.* As such, FDA determined that Lilly's "supply will meet or exceed projected demand." *Id.*

In addition to the data provided by Lilly, FDA also considered information from "patients, healthcare providers, and others, including compounders, along with data from other sources that [FDA] independently identified." Decl. Order 2. FDA determined that this information "ha[d] important limitations" and thus "[did] not undermine or outweigh" Lilly's evidence that its supply was currently meeting or exceeding demand and would also likely meet or exceed

[1] For simplicity, the term "tirzepatide" in this brief generally refers to the products declared to be in shortage in December 2022 and April 2024, and does not include other tirzepatide products that have not been declared to be in shortage.

projected demand. *Id*. FDA thus declared the shortage of Mounjaro and Zepbound resolved. *Id*. at 12. FDA also announced temporary enforcement discretion which, together with commitments Defendants made in connection with this lawsuit, means that FDA will temporarily exercise enforcement discretion for certain violations relating to compounding tirzepatide injection products. *See id.* at 3. The Declaratory Order was supported by a decision memorandum laying out in detail the agency's analysis and conclusions. *See* Mem.

On January 28, 2025, Plaintiffs filed a preliminary injunction motion. ECF No. 64 (Mot.).

LEGAL STANDARDS

A preliminary injunction is an extraordinary remedy that should only be granted "if the movant shows: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction is not granted; (3) the threatened injury will outweigh any harm that will result to [a] non-movant if the injunction is granted; and (4) the injunction will not disserve the public interest." *Ridgely v. FEMA*, 512 F.3d 727, 734 (5th Cir. 2008). The third and fourth factors merge when the government is the party opposing the motion. *Nken v. Holder*, 556 U.S. 418, 435 (2009). A preliminary injunction "should not be granted unless the [movant] has clearly carried the burden of persuasion on all four requirements." *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 268 (5th Cir. 2012) (quotation marks and citation omitted); *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (requiring a "clear showing").

ARGUMENT

I. Plaintiffs Have Not Shown a Likelihood of Success on the Merits

Plaintiffs have not met their heavy burden of demonstrating the likelihood that FDA acted arbitrarily or capriciously, or that it was error to proceed by adjudication rather than notice-and-comment rulemaking.

A. FDA reasonably determined that the tirzepatide shortage was resolved

Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024). "Arbitrary and capricious review focuses on whether an agency articulated a rational connection between the facts found and the

decision made." *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 971 (5th Cir. 2023). The "focal point" of review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). On this "narrow" scope of review, courts "determine only whether the [agency] examined 'the relevant data' and articulated 'a satisfactory explanation' for [its] decision," and courts "may not substitute [their] judgment for that of the" agency. *Dep't of Com. v. New York*, 588 U.S. 752, 773 (2019) (internal quotations omitted).

Plaintiffs have not shown a likelihood that they can meet this demanding standard. The question before FDA was whether Lilly's tirzepatide products were "in shortage in the United States." 21 U.S.C. § 356e(a). A "shortage" is "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id*. § 356c(h)(2). As FDA explained in its decision memorandum, when determining whether a drug is in shortage, "FDA analyzes the supply and demand or projected demand of the drug on a nationwide level, across the entire market, not at the local level." Mem. 3. After thoroughly considering a host of data provided by Lilly over the course of months, as well as information from other sources, FDA reasonably concluded that the data showed that "[Lilly's] supply [was] currently exceeding demand and will meet or exceed projected demand across all strengths of Mounjaro and Zepbound," and thus determined that the shortage was resolved. *Id.* at 5.

With respect to current demand, FDA first examined Lilly's stock reports (data on Lilly's inventory and orders for its tirzepatide products, broken down by dosage strength), and found that they "demonstrate[d] that Lilly ha[d] been filling wholesale orders as they [were] received while generally maintaining product in inventory net of open orders." Mem. 5. Lilly explained that "it does not—and has not—limited the ability of any wholesaler to place orders for any quantities" of its tirzepatide products. *Id.* at 5–6. While Lilly had reported [redacted] it had [redacted]. *Id*. In addition, Lilly's data showed that it had on hand over [redacted] doses of

semi-finished products—products that were manufactured but not yet labeled or packaged—which FDA found "provide[d] assurance that Lilly will continue to be able to fill orders as they are received." *Id*. Lilly's data on cumulative supply and demand further demonstrated that cumulative supply for Mounjaro and Zepbound in 2024 had exceeded demand for all dosages by [redacted]n doses. *Id*. at 7–8. Finally, FDA found that wholesale distributors and retail pharmacies had additional inventory on hand. *Id.* at 11. And [redacted] *Id*. As such, FDA found that [redacted] *Id*.

FDA also concluded that Lilly's supply would meet or exceed projected demand. As FDA explained, Lilly projected demand based on [redacted], among other factors. Mem. 13. Lilly's supply projections were based on [redacted]. *Id.* at 13 n.53. Lilly projected that, [redacted] *Id.* at 15. FDA noted that [redacted] *Id*. at 14. FDA thus concluded that, "based on our best judgment looking at the available information with its limitations, [Lilly] will meet or exceed projected demand across all strengths of Mounjaro and Zepbound." *Id*. at 15.

FDA also considered supply and demand-related information from a variety of other sources, including Plaintiffs and individual patients and pharmacies, as well as news articles and blog posts, comments submitted to FDA's compounding docket, and reports of high volume of demand for compounded tirzepatide. Mem. 16–21. This information included, for example, submissions regarding individual patients' inability to access Mounjaro or Zepbound, *id*. at 16–17, and screenshots from wholesalers' websites indicating that Mounjaro or Zepbound products were out of stock or limited in the amount that could be ordered, *id*. at 19–21.

The agency "carefully evaluat[ed] this information" but determined that it had "important limitations," Mem. 2, and thus "[did] not undermine or outweigh . . . the detailed quantitative picture of the supply and demand situation both over time, and at the national level," that Lilly's data provided, *id*. at 19. For example, many submissions from individual patients had no indication of *when* the patient had trouble accessing tirzepatide products. Nor did these reports use any consistent definition for what it meant to have trouble accessing a drug, a concept that could encompass, for many of the reports, not just an out-of-stock prescription, but also an inability to get a prescription from a doctor or an inability to get insurance coverage for the drug. *Id*. at 17–18. Moreover, FDA noted Lilly's explanations that gaps in availability at individual pharmacies were likely caused by the "practical dynamics" of the supply chain between Lilly's production and the end user, rather than a national shortage of the products. *Id.* at 18. FDA similarly reasoned that the same dynamics most likely explained the screenshots of wholesalers' websites that purported to indicate that wholesalers were restricting sales of Lilly's products or that they lacked inventory. *Id.* at 19–21.

FDA also considered potential future increased demand from some patients receiving compounded tirzepatide transferring their prescriptions to Lilly's product. The agency "recognize[d] that significant compounding of tirzepatide injection products is occurring, and that some patients currently receiving those products can be expected to seek Lilly's approved products at a future point when compounding is curtailed." *Id*. at 27. As FDA explained, there was limited information available about the volume of products that compounders were producing. *Id.* at 24–26. But the agency acknowledged the limitations of the data, made conservative assumptions for purposes of its decision (*e.g.*, by assuming that submitted numbers were accurate and adding all available estimated volumes together), and noted that even the most generous estimate the agency could make of the total volume compounded "would represent a very small amount" compared to Lilly's supply of over [redacted] per month and substantial finished and semi-finished product inventory. *Id*. FDA also observed that some patients receiving compounded tirzepatide would not start treatment with Lilly's products for a

variety of reasons, including that Lilly's products were significantly more expensive than the compounded products. *Id.* at 26–27. FDA thus reasonably predicted, based on the information available, that Lilly's supply would be able to accommodate any increased demand from patients currently receiving a compounded product and that the information from other sources "does not alter [its] conclusions" regarding Lilly's ability to meet current and projected demand. *Id*. at 16.

Plaintiffs fault FDA's decision, claiming that the agency misinterpreted Lilly's data and failed to properly take into account evidence of shortage from other sources. FDA did neither.

1. Lilly-Provided Data. Plaintiffs first claim that FDA erred by considering Lilly's data in cumulative "year-to-date" fashion and that FDA should have looked at the data for each month *in isolation*. Mot. 14–18. If FDA had looked at Lilly's evidence of production and demand per month, Plaintiffs claim, the agency would have concluded that Mounjaro and Zepbound remain in shortage because [redacted] But Plaintiffs' approach would require FDA to ignore [redacted] *See also* Mem. 7 ([redacted]). And there is ample evidence to refute the notion that FDA somehow misunderstood what "cumulative" meant: FDA used the word 18 times in describing this data, *id.* at 1–15, applied its meaning, *id*. at 7 (Lilly "has supplied more than [redacted] . . . *since the beginning of 2024*"), and had a detailed back-and-forth with Lilly on the subject, *e.g.*, AR426, AR476–77.[2] FDA's focus on the data reported for [redacted] as a basis to compare earlier *projected* to later *actual* numbers in no way suggests otherwise, *contra* Mot. 1, 5, 15, as FDA was merely looking to test the accuracy of Lilly's forecasts, for which cumulativeness made no difference. Mem. 14–15 & n.57.

[2] The "AR" numbers refer to the Bates-stamped pages from the certified Administrative Record in this case. *See* ECF No. 76. The relevant record pages are attached hereto as Exhibit 1.

Plaintiffs also claim that "[n]o evidence supports" Lilly's representation that it was able to supply over [redacted] of Mounjaro and Zepbound per month. Mot. 18. But Plaintiffs acknowledge that Lilly had historic monthly supplies as high as [redacted]—and they can avoid Lilly's reasonable projection that it would have [redacted] in [redacted] only by *omitting* Lilly's projections for [redacted] from Plaintiffs' Tables A and B. *Compare id*. *with* Mem. 10, 15.[3] In its [redacted] letter to FDA, Lilly explained that it had made [redacted] AR460. It was thus reasonable for FDA to credit Lilly's assertion about its supply capability.

Plaintiffs' further attempts to comb the decision for possible inconsistencies that FDA allegedly "missed," Mot. 17–19, go nowhere. FDA was not "confus[ed]" about Table 1, *id.* 18; that table reported "inventory *net* of open orders," consistently described as such, and was accurately considered "excess" inventory, Mem. 5–7; *see also* AR575. While Plaintiffs claim that the stock report for [redacted] is "implausible,' Mot. 19 & n.12, Plaintiffs again miss that net inventory carries into the next month (here, [redacted], Mem. 7) and ignore that Lilly also continued to manufacture more doses. Plaintiffs commit the same errors when questioning the supply information (doses shipped) listed in Table 5, Mot. 17, since they again fail to account for Lilly's existing inventory as shown, *e.g.*, in Table 1, Mem. 7 (showing net inventory of [redacted]). And Plaintiffs wrongly accuse FDA of "indulg[ing]" Lilly and accepting Lilly-provided information that allegedly "thwart[ed] interpretation." Mot. 17, 19. But FDA reviewed Lilly's responses with a critical eye and asked for further data and explanations regarding potentially conflicting sources

[3] Lily reported a cumulative supply of [redacted] and projected a cumulative supply of [redacted], meaning that Lilly expected to have [redacted]. Mem. 10, 15.

of information, such as the screenshot evidence that, according to Plaintiffs and others, indicated products were out of stock or limited in availability. Mem. 5–15; *e.g.*, AR453, AR466–77.

Finally, Plaintiffs suggest that the statute requires FDA to identify and analyze a single precise window of time to find a shortage resolved, Mot. 14, 18, but the statute requires no such thing. FDA kept the "list of drugs" it "determine[d] to be in shortage" "up-to-date," 21 U.S.C. § 356e(a), by finding that the "period of time" when supply of tirzepatide failed to meet demand was over, *id.* § 356c(h)(2). In doing so, FDA carefully considered and analyzed information in the record and reasonably found that available evidence supported that conclusion. The APA requires no more.

2. Other Information. Plaintiffs also fault FDA for its interpretation of other evidence alleging a shortage. Mot. 19–21. But as explained above, *see supra* pp. 8–9, FDA considered the anecdotal evidence of wholesaler unavailability and patient reports and found that it had important limitations, including lack of specificity regarding why a patient had trouble accessing the product, and lack of information regarding the length of time the product was out of stock or limited in availability. Mem. 16–22. The news reports similarly contained anecdotal reports of difficulty obtaining GLP-1 products but lacked "probative evidence" relevant to whether the nationwide shortage had been resolved. *Id*. at 21. FDA confronted Lilly with the very possibilities Plaintiffs now invoke. *See*, *e.g.*, AR454. Lilly provided data on wholesaler inventory, explained the supply chain dynamics at work, and, critically, confirmed that it was not limiting wholesaler orders. AR462–71; *see also* Mem. 20. Lilly also [redacted] AR468–69; Mem. 21. FDA reasonably found that anecdotal reports of a low supply or even isolated unavailability of Lilly's products were more likely due to localized factors and not a nationwide shortage. Mem. 16–21.[4]

[4] Plaintiffs identify a random smattering of other public information they allege FDA failed to adequately consider, Mot. 21, but none of it casts doubt on FDA's conclusions. For example, Plaintiffs cite "a Big Three wholesaler" statement that provided no actual data and discussed

Contrary to Plaintiffs' assertion, a shortage does not exist for FDCA purposes every time "patients cannot get the product" for any reason. Mot. 20. Although the statute recognizes a "delay[] in shipping" as one possible reason a drug may be in shortage, 21 U.S.C. § 356e(b)(3)(F), as explained above, the touchstone of the statutory analysis is nationwide supply and demand. To be sure, a delay in shipping could be so significant that it could affect supply on a nationwide level, such as when a natural disaster decimates a product's sole manufacturing site. But Congress clearly did not intend any interruption in shipping, anywhere in the supply chain, to automatically constitute a shortage "within the United States." *Id.* § 356c(h)(2).

Finally, Plaintiffs claim that FDA failed to afford due consideration to the sales volume of compounded tirzepatide. Mot. 21–23. Specifically, Plaintiffs claim that FDA "erroneously deemed compounded products irrelevant," "disregard[ed] demand for compounded products because they beat Lilly's on price," failed to take into account the correct volume of compounding, and incorrectly assumed that some patients were using compounded tirzepatide for off-label uses. *Id.* To the contrary, FDA did not deem compounded products "irrelevant." *Id.* FDA explained that, while it found the volume of compounded products to be of "minimal relevance" to *current* demand,[5] it found such volume relevant to *projected* demand, "which

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"GLP-1s" generally, a category that includes drugs other than tirzepatide that are currently on FDA's shortage list. Pls. Ex 6 at 14. Plaintiffs also point to a statement by the home delivery pharmacy Express Scripts that it "is no longer taking new GLP-1 patients because of market demand," but the cited article attributes that generalized statement to PBMs (Pharmacy Benefit Managers) "los[ing] money on filling GLP-1 prescriptions" and insufficient reimbursement, not a shortage. Pls. Ex. 12. Indeed, FDA noted that PBM network decisions were one reason that retail pharmacies may not always fill every prescription presented to them. Mem. 18. Plaintiffs' reliance on the American Society of Health-System Pharmacists' (ASHP) shortage list is also inapposite because it uses different criteria than those in the FDCA, *see* ASHP, *FDA and ASHP Shortage Parameters*, https://perma.cc/F6FB-HRBE, and, in any event, ASHP currently lists tirzepatide injection products as "available," https://perma.cc/PG4K-YJWD.

[5] Plaintiffs argue that compounded products must be considered part of the current demand for tirzepatide. Mot. 21. But if compounded product becomes part of "demand," it must also become part of "supply," and shortages would repeatedly toggle on and off. *See* Mem. n.103. Plaintiffs also speculate that FDA's approach would allow a manufacturer to "end shortages simply by raising prices or limiting supply." Mot. 22. To the contrary, manufacturers resolve shortages by

among other things considers the possible effect of the curtailing of compounding on demand for Lilly's products in the future." Mem. 22–23. FDA then evaluated it in depth. *Id*. at 23–28.

Plaintiffs generally do not dispute as a factual matter FDA's prediction that, for a variety of reasons, demand for compounded products would not translate "one-for-one" into demand for Lilly's products once the shortage was resolved, and that there remained "considerable uncertainty about" the scope of that effect. *See* Mem. 26–27. With respect to the cost of the products, FDA noted that compounders had been providing tirzepatide at one-half or even one-quarter of the cost of Lilly's products, and that insurance might not cover uses of Lilly's products for which patients were currently obtaining compounded product. *Id*. at 26 n.116, 27. The agency thus reasonably concluded that, as to the forthcoming transition period, "[f]uture demand is likely to be affected by the prices consumers face." *Id*. at 26. The rest of Plaintiffs' arguments that FDA undercounted the actual volume of compounding must be viewed in that light.

Nor did FDA err in its analysis of the limited information before it regarding the volume of compounding. FDA reasonably considered outsourcing facility numbers for the first half of 2024 because that was "the most recent complete reporting period." Mem. 24–25.[6] Moreover, FDA considered OFA's statements that its "members ha[d] produced hundreds of thousands of doses . . . in September 2024." *Id.*; *see also* ECF No. 67 at 18 (Rosebush Decl. ¶ 69) (a new estimate not before the agency at the time of the decision that is not substantially different). But "[e]ven assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory." Mem. 24. FDA similarly did

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increasing supply, not limiting it, which is precisely what Lilly did here during the two-year duration of the shortage.

[6] Plaintiffs are correct that FarmaKeio is not an "outsourcing facility" but are wrong to call FDA's interpretation of FarmaKeio and outsourcing facilities' submissions "absurd." Mot. 22. While they say FDA "apparently" made a mistake, Plaintiffs do not identify the supposedly correct way to interpret their information. *Id.* In any event, even if FDA overestimated the extent of FarmaKeio's volume of compounding, including by counting it towards outsourcing facilities' numbers, that mistake only added to the volume of compounded product FDA considered, reinforcing that FDA's conclusions were conservative.

not "ignore" 503A compounders' assertions that they were collectively dispensing 125,000 prescriptions per month. *Contra* Mot. 22 & n.15.[7] In fact, FDA explicitly assumed the accuracy of those assertions, including the claim that the number was an undercount, and still found them outweighed by Lilly's supply data. Mem. 26.

Ultimately, FDA acknowledged that "significant compounding" was occurring, considered the extent to which compounding might translate to future demand, and concluded that Lilly likely would meet or exceed projected demand. *Id*. at 24–27. This conclusion was eminently reasonable given that Lilly was currently meeting or exceeding demand, had ramped-up its supply capabilities to [redacted] per month, and had substantial inventories of its approved products (over [redacted]—which Plaintiffs' motion wholly ignores).

At bottom, FDA's decision reflected a more than reasonable judgment based on the information available. *See Prometheus*, 592 U.S. at 427 (2021) ("the FCC made a reasonable predictive judgment based on the evidence it had"). Plaintiffs are not likely to show otherwise.

B. FDA's declaratory order was consistent with the APA

FDA's shortage determination was a classic adjudication under the APA because it used the statutory definition of "shortage" to resolve a discrete controversy. Plaintiffs' arguments to the contrary inaccurately portray the nature of a drug shortage determination and rely on inapposite case law. And even if Plaintiffs were correct that notice-and-comment was required, any error would be harmless: FDA provided ample opportunity for Plaintiffs and others to submit information, which FDA considered in its shortage determination.

[7] Plaintiffs say information in a letter from the Alliance for Pharmacy Compounding "should have prompted the agency to investigate." Mot. 22 (citing Plaintiffs' Ex. 39 (erroneously cited as "Ex. 40")). But this argument ignores the elementary principles that "[t]he APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies" and that review under the APA is limited to "evidence" the agency "had" at the time of its decision. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021).

1. FDA properly issued a declaratory order

A. FDA properly issued its shortage determination through adjudication. The "line between" adjudication and rulemaking "is frequently a thin one." *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 83 F.2d 1029, 1030 n.2 (D.C. Cir. 1989). But the "basic distinction between" the two is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). The decision to proceed by adjudication rather than rulemaking "'is one that lies primarily in the informed discretion of the administrative agency,'" *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)), and that decision is reviewable for an abuse of discretion, *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). An agency's judgment that there is "reason to . . . develop[] its standards in a case-by-case manner" with attention to the specific facts of each case "is entitled to great weight." *Id*. Declaratory orders have binding legal effect and allow agencies to efficiently apply existing policy to a set of facts without the need for any particular party to risk penalty or sanction to resolve a dispute. *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012); *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 536–37 (D.C. Cir. 2007).

Here, the discrete nature and context of FDA's shortage determination demonstrate that FDA properly used adjudication to determine whether there was a tirzepatide shortage and properly issued a declaratory order to resolve that controversy. *See*, *e.g.*, *Am. Airlines, Inc. v. Dep't of Transp.*, 202 F.3d 788, 796–97 (5th Cir. 2000) (affirming agency's decision to issue a declaratory order through adjudication). FDA applied the statutory definition of shortage to "a particular set of disputed facts," *Fla. E. Coast Ry.*, 410 U.S. at 246—namely, to data demonstrating the current and projected nationwide supply and demand of tirzepatide, 21 U.S.C. § 356c(h)(2). Whereas the agency had applied the same statutory definition to find that there was a shortage in December 2022, new data led FDA to conclude that the shortage had been resolved

by December 2024. The only difference was the evidence, demonstrating that FDA decided "each case upon individual grounds," *Fla. E. Coast Ry.*, 410 U.S. at 245 (citation omitted), and applied the law consistently on "a case-by-case" basis, *Bell Aerospace*, 416 U.S. at 291–94.[8]

FDA's shortage determination had none of the characteristics of a rule. FDA's conclusions about the highly factual issue of availability of particular drugs manufactured by a single company are not "applicable across the board" nor "generalized [in] nature." *Fla. E. Coast Ry.*, 410 U.S. at 246. Nor were the agency's factual findings "used in the formulation of a basically legislative-type judgment." *Id.* And in contrast to the purely "prospective application" of a rule, *id.*, FDA's adjudication determined "present rights and liabilities" by finding that there was not *presently* a shortage, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring) (quoting Attorney General's Manual on the APA 14 (1947)).

B. The statutory scheme does not specify what procedure FDA must use to make shortage determinations and thus gives FDA the discretion to choose whether to proceed through adjudication or rulemaking. FDA appropriately concluded that adjudication was the only viable option for multiple reasons, especially under the circumstances of this case. Decl. Order 5. First, Congress requires the list to be "up-to-date." *Id.* at 8 (citing 21 U.S.C. § 356e(a)). The list must therefore "extend[] up to the present time" and "us[e] or includ[e] the latest facts." *Up-to-date*, Merriam-Webster New World College Dictionary (4th ed. 2009). Here, FDA satisfied this mandate by considering supply-and-demand data submitted throughout fall and winter 2024 to reach its shortage determination. *See* Mem. 5 n.16. Even expeditious notice-and-comment rulemaking would have precluded such timely action, and potential variations on those procedures, such as use of the "good cause" exemption, would present their own challenges. Decl. Order 8.

[8] Plaintiffs notably neglect to acknowledge the necessary implication of their argument: If shortage resolution decisions require rulemaking, so must shortage listing decisions, which would impose a significant barrier to FDA's ability to timely identify a new shortage for potential compounding.

Second, engaging in meaningful notice-and-comment was not possible in these circumstances, where the manufacturer has maintained as confidential the core set of facts material to the decision. To satisfy the APA's requirement that a proposed rule "give interested persons an opportunity to participate," 5 U.S.C. § 553(c), an agency must "reveal[] for public evaluation" the "technical studies and data upon which the agency relies," and in particular, "the most critical factual material used by the agency," *Chamber of Com. v. SEC*, 443 F.3d 890, 899–900 (D.C. Cir. 2006) (internal quotations omitted). An agency therefore "commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991). In the circumstances of this case, the most critical factual material was the manufacturer's confidential business information, all of which FDA is prohibited from disclosing. *See*, *e.g.*, 21 U.S.C. §§ 331(j), 356e(c)(2); 21 C.F.R. § 314.81(*b*)(2)(vii)(b). Consequently, FDA could not issue a proposed shortage list rule that "reveal[s] for public evaluation" the "most critical factual material" upon which it relies. *Chamber of Com.*, 443 F.3d at 899–900.

Third, Congress also gave FDA the discretion to withhold information that is not confidential, including the very *existence* of a shortage. 21 U.S.C. § 356e(c)(3). The public-health exception authorizes FDA to "choose not to make information" on the shortage list public if it "determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients)." *Id*. That provision is fundamentally incompatible with public notice and comment. In at least those cases, FDA *must* proceed by adjudication.

C. Even if the Court concludes that FDA's shortage determination was a "legislative rule," notice and comment was not required because the drug shortage provision's requirements displace the APA's notice-and-comment requirements by necessary implication. While Plaintiffs emphasize that the APA requires that exceptions to its procedures be made "expressly," 5 U.S.C. § 559, the Supreme Court has "long recognized" that this language "creates what is in effect a less demanding interpretive requirement"—a "background principle of interpretation." *Dorsey v.*

United States, 567 U.S. 260, 273–74 (2012). A later Congress is empowered "to make its will known in whatever fashion it deems appropriate," *Lockhart v. United States*, 546 U.S. 142, 148 (2005) (Scalia, J., concurring), including by "necessary implication." *Dorsey*, 567 U.S. at 274. As already discussed, given these facts, the drug shortage statute's provisions governing listing are "so clearly different from those required by the APA that [Congress] must have intended to displace" notice and comment. *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998).

2. Plaintiffs are wrong that FDA had to proceed by rulemaking

Ignoring the limited and fact-specific nature of FDA's shortage determination, Plaintiffs claim that it "create[d] law by prohibiting all compounding of tirzepatide" and that it was therefore a "rule." Mot. 8. They assert that the decision was "no different in its force and effect than if Congress had enacted a statute prohibiting that activity," *id.*, ignoring that Congress did enact just such a statute—the FDCA—and FDA's decision creates no new law. Plaintiffs draw a series of false distinctions between adjudications and rules and rely on inapplicable case law.

A. Plaintiffs first protest that FDA's shortage determination affects the rights of "thousands" of entities, suggesting that a broad impact transforms an adjudication into a rulemaking. *Id.* at 9. But "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999); *see Qwest*, 509 F.3d at 536 (FCC's "broadly applicable order" that determined the classification of all IP-transport and menu-driven calling cards was an adjudication); *Chisholm v. FCC*, 538 F.2d 349 (D.C. Cir. 1976). And contrary to Plaintiffs' arguments, Mot. 9, courts have long recognized that "an agency need not be presented with a specific dispute between two parties" to issue a declaratory order. *City of Arlington*, 668 F.3d at 243.

FDA routinely conducts adjudications that yield orders affecting large numbers of third parties, and especially competitors, in a highly regulated area: the new drug approval process. *See* 21 U.S.C. §§ 355(d)–(g). An approval of a new drug triggers certain statutory restrictions on compounding drugs that are essentially copies of "approved drugs"—including the very same

one that Plaintiffs now invoke. *See id*. §§ 353b(a)(5), (d)(2)(A). And an approval can have numerous other effects on potential competitors, such as blocking all others from obtaining approval for any drug containing its same active moiety for five years (as Mounjaro's did here). *See id*. § 355(c)(3)(E)(ii). Yet none of this makes drug approvals legislative rules. *See also Weinberger v. Hynson, Westcott and Dunning Inc.*, 412 U.S. 609, 624–26 (1973) (endorsing FDA use of declaratory orders to address "several persons or manufacturers" of generic drugs sharing common considerations).

Next, Plaintiffs contend that FDA's shortage determination cannot be an adjudication because it has "purely prospective" effects, pointing to the portion of FDA's order that discusses the agency's intentions with respect to enforcement discretion. Mot. 10. But it is unremarkable that an adjudication "may affect agency policy and have general prospective application." *Conf. Grp., LLC v. FCC*, 720 F.3d 957, 966 (D.C. Cir. 2013) (quotation omitted). And as already discussed above, FDA's shortage determination was not "purely" or even primarily prospective: the enforcement discretion included in the decision only has occasion to exist because the decision determined "present rights and liabilities" established by operation of the FDCA. *Bowen*, 488 U.S. at 221 (Scalia, J., concurring) (citation omitted). By contrast, the discussion of enforcement discretion is not legislative in nature; it creates no new law and simply expresses that the agency "does not intend to take action" against compounders for certain types of violations before certain dates. Decl. Order 9. FDA could have achieved the same result by not taking legal action against compounders during the relevant time period without stating the agency's intentions in advance.

For similar reasons, Plaintiffs' comparison to *Safari Club International v. Zinke*, 878 F.3d 316 (D.C. Cir. 2017), is inapt. Mot. 10. Plaintiffs in that case challenged decisions of the U.S. Fish and Wildlife Service that had the effect of banning *future* importation of certain elephant trophies. *Safari Club*, 878 F.3d at 333. Importantly, those decisions "applied to all potential imports of sport-hunted elephant trophies from Zimbabwe, not to any individual parties . . . and did not adjudicate any dispute between specific parties." *Id.* at 333–34. Applying the principle

that "adjudications immediately bind parties," whereas rules have "only future effect," the D.C. Circuit held that the decisions were rules. *Id.* at 333 (citing *Bowen*, 488 U.S. at 216–17). Unlike in that case, and as Plaintiffs emphatically reiterate, the statutory consequences of FDA's shortage determination immediately apply to specific parties, causing Plaintiffs to cease ongoing conduct and causing their products to be "forced off the market," Mot. 2, 23. And that effect only comes by operation of the existing statute, not by creating new legislative standards that govern individual rights and liabilities. FDA's decision does not govern any future shortage decisions, whether specifically with respect to tirzepatide or more generally. FDA will need to continue to make each such decision on a case-by-case basis. *See*, *e.g.*, *Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of adjudicating a particular set of disputed facts").

Likewise, Plaintiffs' reliance on cases involving IRS "agency listing decisions" misses the mark. Mot. 8 (citing *Green Rock LLC v. IRS*, 104 F.4th 220 (11th Cir. 2024); *Mann Constr., Inc. v. United States*, 27 F.4th 1138 (6th Cir. 2022)). Those cases bear no resemblance to FDA's shortage determination. Unlike FDA's highly fact-bound decision here, the IRS "create[d] new substantive duties" for an entire class of transactions, divorced from the facts of any particular transaction. *Mann*, 27 F.4th at 1144. Further, the IRS did not argue that it was conducting adjudications; at issue was whether the IRS listings were interpretive rules (which do not require notice and comment) or legislative rules. The other decisions Plaintiffs cite are similarly inapposite because they do not address the distinctions between rulemaking and adjudication. *See* Mot. 8.

B. Plaintiffs fail to explain how meaningful notice-and-comment rulemaking would have been possible in the circumstances of this case. Plaintiffs do not dispute that FDA's shortage determination centers on a core set of confidential facts that the agency cannot disclose, to a degree that it would be unlikely to provide the public with a "meaningful" opportunity to

comment if FDA were to publish a proposed rule based on a mostly, or entirely, confidential record. *Solite Corp.*, 952 F.2d at 484. Nor do they contest that the statute permits FDA to *withhold* the very *existence* of a shortage if disclosure would adversely affect the public health. *See* 21 U.S.C. § 356e(c)(3). Plaintiffs do not dispute that meaningful notice-and-comment rulemaking could not take place in such circumstances. Mot. 12 (citing 5 U.S.C. §§ 553(b)(B), 552(b)(3)). This is not surprising, since it defies logic to suggest that the shortage statute, which requires FDA to keep confidential the most critical factual material on which its decision rests and authorizes the agency to decline to announce its decision at all, is *also* subject to public notice and comment procedures.

In short, Plaintiffs' argument that FDA was required to proceed through notice-and-comment rulemaking is estranged from the plain language of the APA, the variety of judicially sanctioned uses of declaratory orders, and the drug shortage authority itself.

3. Any procedural error was harmless

Even if FDA's determination that the shortage was resolved should have been subject to notice and comment, any error would be harmless. *See* 5 U.S.C. § 706. If an agency errs by not following notice-and-comment procedures, the error is harmless if "the lack of notice and comment did not prejudice" plaintiffs. *City of Arlington*, 668 F.3d at 244. That is the case here.

As early as August 2024, through updates submitted to the agency's public drug shortages website, Lilly indicated that it believed the shortage had ended. *See* Mem. 4 & n.15. Two months after that, FDA notified the public about its initial determination through its website. Decl. Order 3, 8. FDA then openly solicited comment and data, ECF No. 27 at 4, and the public had more than two-and-a-half months to submit information. Though FDA was unable to disclose the most critical factual material, FDA "received and considered comments from" a variety of "interested parties," *City of Arlington*, 668 F.3d at 245, including from individual patients, pharmacy compounders, outsourcing facilities, trade associations, and telehealth companies, *see* Decl. Order 9–10. Because Plaintiffs "received notice of the issues pending before [FDA] and had the ability to comment on [them] in the agency proceedings," and FDA already "considered and

addressed" the issues raised in this litigation, Plaintiffs suffered no prejudice from a lack of notice and comment. *City of Arlington*, 668 F.3d at 245–46.

Plaintiffs speculate that publishing notice in the Federal Register *might* have led to additional public comments, Mot. 12–13, but they identify no one who claims to have missed out on the chance to comment. With good reason: FDA notified the public of its initial determination, the agency's reevaluation made national headlines,[9] and the agency had already received and considered information from the drug's manufacturer and the major trade groups for compounding pharmacies. *See*, *e.g.*, Mem. 5–15, 17–20. And as FDA noted, *id.* 26., Lilly's expected surplus dwarfed the agency's generous estimate of the potential volume of compounded tirzepatide by [redacted], indicating that hypothetical additional information from unknown third parties would not have changed the outcome.

Plaintiffs also fault FDA for allegedly using a "new methodology" in its shortage determination, deride that method as "idiosyncratic," and claim that a notice of proposed rulemaking would have informed interested parties as to the "kinds of information the agency would consider." Mot. 12–13. There was no mystery here. The statute required FDA to determine whether nationwide supply of Lilly's product could satisfy current demand and projected demand, 21 U.S.C. § 356c(h)(2), so detailed nationwide supply-and-demand data are obviously most useful, *e.g.*, Mem. 4–5. Conversely, anecdotal experiential reports from individual consumers, or unscientific internet polls, are inherently less reliable or probative. *Id.* 16–29.[10] And even if FDA had employed a new methodology in its shortage determination, orders often discuss, apply, and interpret legal standards which may independently apply to future actions in similar situations. *See Qwest*, 509 F.3d at 536– 37. Plaintiffs had the opportunity to submit

[9] *See, e.g.*, Reuters, US FDA to reconsider decision barring compounded versions of Lilly weight loss drug (Oct. 11, 2024), https://www.reuters.com/business/healthcare-pharmaceuticals/fda-reconsider-decision-barring-compounded-versions-lilly-weight-loss-drug-2024-10-11/.

[10] FDA publicly endorses the government-wide "[t]ips for submitting effective comments," including to "support your comment with substantive data, facts, and/or expert opinions." Regulations.gov, Tips for submitting effective comments, https://perma.cc/F9UD-96NB.

information, were not limited in doing so, and in fact submitted as many comments as they wished, making clear that the absence of notice-and-comment procedures did not prejudice them.

In sum, FDA properly proceeded by adjudication and declaratory order. And even if the Court were to determine otherwise, any error was harmless. Plaintiffs are thus not likely to succeed on the merits of their procedural claim.

II. The Balance of Equities and Public Interest Strongly Weigh Against Injunctive Relief

Denying the proposed injunction serves the public interest because it would maximize patient safety and give effect to the balance Congress struck between incentivizing drug development and allowing compounding during temporary drug shortages. Neither Plaintiffs' economic interests in continuing to market compounded tirzepatide nor concerns about patient access outweigh those concerns. For this reason, too, Plaintiffs' motion should be denied.

Compounded drugs do not provide patients with the full complement of safety protections that Congress made generally applicable to conventionally manufactured drugs. As FDA's decision observed, compounded drugs "have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process." Mem. 10. Products from 503A pharmacies offer yet fewer safety assurances to patients because they are not required to comply with cGMP regulations that help ensure the quality of pharmaceuticals, *id.*, nor are they subject to the statutory adverse event reporting requirements that apply to outsourcing facilities. Plaintiffs claim that patients have suffered minimal safety consequences from their compounded products, which, if accurate, is no doubt a good thing. Mot. 25. But the public has an interest in—and the statute requires—the assurance provided by FDA's thorough premarket review process and cGMP requirements.[11]

[11] Plaintiffs cite the FDA Adverse Event Reporting System (FAERS) and claim that it shows that Lilly's "tirzepatide products caused more than 28,000 adverse-incident events in 2024." Mot. 25. That claim is highly misleading because the information in FAERS reports has not been verified, does not establish causation between the drug and the reported adverse event, and is many times duplicated or incomplete.

In addition, an injunction of any length would undercut the balance Congress struck between incentivizing conventional drug manufacturers to develop innovative drugs and the public's need for supplemental supplies of those drugs during shortages. Congress determined that Lilly and others in the same position should be entitled to a five-year window in which they have the exclusive right to market the drug they developed. 21 U.S.C. § 355(c)(3)(E)(ii). Unnecessarily prolonging the period in which compounders may produce copies of an FDA-approved drug diminishes these statutory rights and, in turn, diminishes incentives for drug development and manufacturing, harming the public's interest in future innovations.

To be sure, as Plaintiffs contend, the public has an interest in having access to medical treatments. *See* Mot. 24. But that interest should not be advanced by contravening Congress's carefully struck balance between incentives for drug development and compounders' occasional and temporary ability to satisfy demand during a shortage. Moreover, in light of Lilly's manufacturing capacity and existing stock of tirzepatide, the public will not be deprived of access to tirzepatide absent injunctive relief. To the extent that the access concerns Plaintiffs invoke are functions of the approved drug's cost and limitations on insurance coverage, they are entirely distinct from the instant factual question of whether the tirzepatide shortage was resolved and thus fall outside FDA's statutory authority to address. *See* Mem. 26 n.116.

Nor is the public interest outweighed by any financial loss to Plaintiffs. The financial opportunity for compounders presented by the tirzepatide shortage was always temporary and subject to FDA's determination that the shortage was over. FDA has afforded Plaintiffs substantial enforcement discretion to facilitate the orderly wind-down of their tirzepatide manufacturing efforts. The public interest and balance of equities weigh heavily against an injunction.

CONCLUSION

Plaintiffs' motion for a preliminary injunction should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent by electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 18, 2025

/s/ *Oliver McDonald*
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